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Research Article

A RANDOMISED CONTROL TRIAL ON *SHIGRUPATRA ARKA ASHCHYOTANA* IN *KAPHAJA ABHISHYANDA*

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ABSTRACT

Eyes are the most essential and delicate organ of the human body and they need special care. Vernal Keratoconjunctivitis (VKC) is recurrent, bilateral, interstitial, self-limiting allergic inflammation of the conjunctiva having periodic seasonal incidence, also known as Warm weather conjunctivitis or Spring Catarrh. Vernal Keratoconjunctivitis (VKC) is an allergic eye disease that especially affects young boys. **Aim:** To study the role and efficacy of *Shigrupatra Arka Ashchyotana* in *Kaphaja Abhishyanda*. **Objectives:** 1. To compare the efficacy between *Shigrupatra Arka Ashchyotana* and olopatadine eye drop (0.1%). 2. To establish a relation between *Kaphaja Abhishyanda* and Vernal Kerato-Conjunctivitis (VKC). **Material and Methods:** 40 patients of *Kaphaja Abhishyanda* were randomly assigned to two groups for a clinical trial. **Result:** The clinical data shows that the effect of therapy on *Kaphaja Abhishyanda* is 73.36% in Group A and 71.79% in Group B. **Conclusion:** It can be concluded that clinically *Shigru Patra arka Aschyotana* is effective in managing the symptoms of *Kaphaja Abhishyanda*.

INTRODUCTION

Vision is a priceless gift given to us from God, eyes are the blessing which ensures to enjoy the beauty of the world. Eyes are the most essential and delicate organ of the human body and they need special care. Therefore, maintaining health of eyes has become very necessary. Now day's lifestyle has become so hectic that people tend to forget to take care of their eyes. Exposure to dust, fumes, pollution and sunlight can cause hypersensitivity reactions which leads to various eyes diseases and vernal Kerato-Conjunctivitis is one of them. Vernal Kerato-Conjunctivitis (VKC) is recurrent, bilateral, interstitial, self-limiting allergic inflammation of the conjunctiva having periodic seasonal incidence, also known as Warm weather conjunctivitis or Spring Catarrh. Vernal Kerato-Conjunctivitis (VKC) is an allergic eye disease that especially affects young boys.

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Most of the conjunctivitis in minor are self-limiting and may not cause serious harm. A need of treatment is essential to reduce the morbidity by reducing the course of the disease and to restore the patient comfort by combating the discomfort and pain of the patient. It is one of the most common eye problems requiring treatment. Acharya *Shushruta* has described 76 eye diseases with their treatment both in medical and surgical ways.[1] Among them *Abhishyanda* comes under the category of *Sarvagata Netra Roga. Acharya Shushruta* has described that *Abhishyanda* is the root cause of almost all eye disorders[2]. *Abhishyanda* is of 4 types *Vataja, Pittaja, Kaphaj, Raktaja*. Out of these four types, the clinical features of *Kaphaja Abhishyanda* as explained in Ayurvedic literature resemble to Vernal Kerato-Conjunctivitis (VKC). In Ayurveda classics, *Snehana, Virechana, Siravedha, Mridu swedana* and *Netra kriyakalpa* like *Aschyotana*, *Seka* and *Anjana* are mentioned in the treatment of *Abhishyanda*[3]. Out of these, *Aschyotana* is a simple procedure, which is indicated in the initial stage of eye diseases. In classics, we get various references about the use of *Shigru* in different forms for *Netra rogas* and also in *Abhishyanda*. *Shigru* has been described in *Kaphaja abhishyanda*[4] and has

Krimighana, *Kaphaghana* and *shothahara* property. Hence, *Shigru* is considered to be a potent, reliable drug in the treatment of *Kaphaja Abhishyanda*.

MATERIAL AND METHODS

Source of Data: 40 patients suffering from *Kaphaja Abhishyanda* who fulfilled the inclusion criteria were selected and placed in two groups by simple randomisation process from OPD & IPD of Shalakya Tantra Department of Patanjali Ayurved Hospital. Each patient provided written consent on a prescribed Performa form. The study was conducted under a strict protocol to prevent bias and to reduce the source of error in the study.

Selection of Cases: 40 patients who attend the O.P.D and I.P.D. of *Shalakya Tantra* Department of Patanjali Ayurved Hospital, irrespective of their religion, sex, occupation, socioeconomic status were selected.

Criteria for Selection of Patient

Inclusion Criteria

1. Patients with classical symptoms of *Kaphaja Abhishyanda* and Vernal keratoconjunctivitis (VKC).
2. Patients between age group of 5 years to 25 years of either sex.
3. Patients with symptoms like itching, photophobia, lacrimation, slimy discharge and heaviness of lids.

Exclusion Criteria

1. Patients less than 5 years and above 25 years of age.
2. Patients having symptoms *of Vataja, Pittaja, Raktaja Abhishyanda*.
3. Patients suffering from any other eye diseases like corneal xerosis, corneal ulcer, dacryocystitis, and infective conjunctivitis.
4. Patients suffering from other systemic disease and metabolic disorders.

Withdrawal Criteria

1. Patients having adverse effect by procedure or medication.
2. Patients having any kind of personal issues.

Laboratory Investigation: CBC, ESR, AEC.

Sites of Study: Patanjali Ayurved Hospital, Haridwar.

Health condition/problem studied: *Kaphaja Abhishyanda*/ Vernal Keratoconjunctivitis (VKC).

Study Design: Open label, controlled randomized clinical study.

Method of Generating Randomization Sequence: Computer generated randomization method.

Blinding /masking: Open label.

Sample Population: All *Kaphaja Abhishyanda* patients reported to Shalakya Tantra OPD.

Sample Size: 20 patients having classical symptoms of *Kaphaja Abhishaynda* in each group.

Phase of trial: 2nd phase

Duration of Treatment: 15 days

Follow up: Follow up is 15 days after completion of treatment.

Grouping:

Group A: This group was treated with *Shigru Patra Arka Ashchyotana*.

Group B: This group was treated with Olopatadine 0.1% eye drop.

Dosage:

Group A: *Shigru patra Arka Aschyotana* was given 8-8 drops three times a day for 15 days.

Group B: Olopatadine 0.1% eye drops[6] was given 2-2 drops twice a day for 15 days.

***Shigru Patra Arka*[5]**

Name	Latin Name	Part Used
Shigru	*Moringa Oleifera*	Leaves

Assessment Criteria

Subjective Parameters

1. *Kandu* (Itching in the eye)
2. *Guruta* (Heaviness in the eye)
3. Watering eyes
4. *Pichhila srava* (Slimy discharge from the eye)
5. Burning sensation
6. Photophobia

Objectives Parameters

1. Palpebral conjunctiva hypertrophy
2. Palpebral conjunctival congestion
3. Bulbar conjunctival congestion
4. Horner-tranta's dots (Limbal area)

Grading System: The effects of therapy before and after the treatment were assessed with the help of following scoring pattern:

***Kandu* (Itching in the Eyes)**

Parameters	Grade
No itching	0
A mild itching, not requiring eye rubbing	1
A definite itching, requiring eye rubbing sometimes	2
An incapacitating itching with significant eye rubbing	3

***Guruta* (Heaviness in the Eyes)**

Parameter	Grade
No heaviness on lids.	0
Occasional heaviness on lids	1
Intermittent heaviness on lids	2
Continuous heaviness on lids	3

Watering Eyes

Parameter	Grade
No watering	0
Slightly watering	1
Occasional watering	2
Tears rolling down cheeks	3

***Pihchila Srava* (Slimy Discharge)**

Parameter	Grade
No watering	0
Slightly watering	1
Occasional watering	2
Tears rolling down cheeks	3

Burning Sensation

Parameter	Grade
No burning sensation	0
Occasional burning sensation not affecting routine work	1
Continual burning sensation affecting routine work	2
Continous burning sensation affecting routine work	3

Photophobia

Parameter	Grade
No photophobia	0
Photophobia only in day light	1
Photophobia in bright light	2
Photophobia even in dim light	3

Palpabral Conjunctival Hypertrophy

Parameter	Grade
No conjunctival hypertrophy	0
Diffuse conjunctival hypertrophy	1
Giant Cobble stone papillae	2
Giant cauliflower like papillae with copious mucus	3

Palpabral Conjunctival Congestion

Parameter	Grade
No congestion	0
Congestion with clear pattern of blood vessels	1
Congestion with poorly visible pattern of blood vessels	2
Velvety conjunctiva with loss of blood vessels pattern	3

Bulbar Conjunctival Congestion

Parameter	Grade
No congestion	0
Muddy color of bulbar conjunctiva	1
Conjunctival congestion visible only in palpebral aperture	2
Conjunctival congestion in entire bulbar conjunctiva	3

Horner-Trant's Dots (Limbal Area)

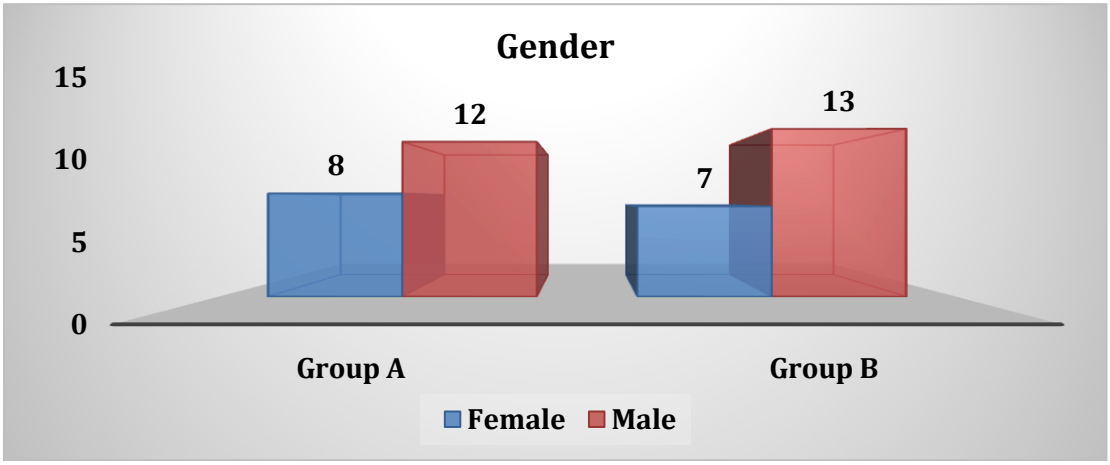
Parameter	Grade
No Tranta's spot	0
Tranta's spot 1-2 in no	1
Tranta's spot 3-5 in no	2
>5Tranta's spot	3

OBSERVATIONS

20 patients were registered in Group A & 20 in Group B were taken and all of them completed the treatment. Distribution of patient based on Gender

Gender	Group A		Group B		Total	
	N	%	N	%	N	%
Female	8	40.00%	7	35.00%	15	37.50%
Male	12	60.00%	13	65.00%	25	62.50%
Total	20	100.00%	20	100.00%	40	100.00%

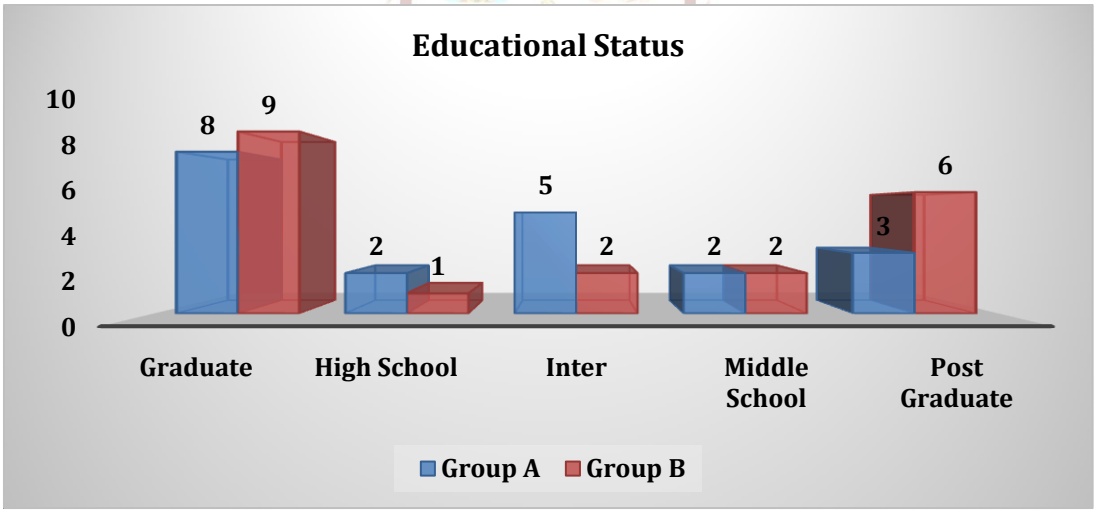
Table shows that maximum number of patients i.e., 25 (62.50%) were male while rest of the patients i.e., 15 (37.50%) were female.



Distribution of Patient Based on Educational Status

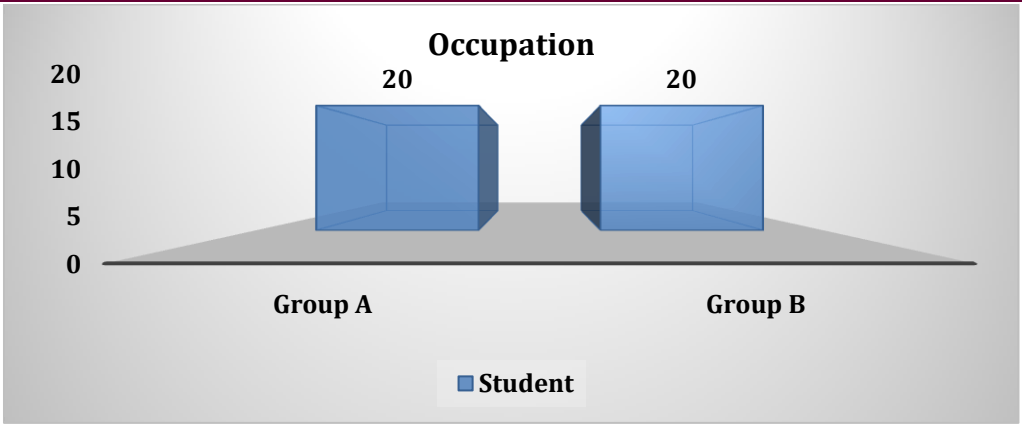
Educational status	Group A		Group B		Total	
	N	%	N	%	N	%
Graduate	8	40.00%	9	45.00%	17	42.50%
High School	2	10.00%	1	5.00%	3	7.50%
Inter	5	25.00%	2	10.00%	7	17.50%
Middle School	2	10.00%	2	10.00%	4	10.00%
Post Graduate	3	15.00%	6	30.00%	9	22.50%
TOTAL	20	100.00%	20	100.00%	40	100.00%

Maximum number of patients i.e., 17 (42.50%) were graduates, followed by post graduate 9 (22.50%), 7 (17.50%) Intermediate, 4 (10.00%) middle school, 3 (7.50%) were high school in education.



Distribution of patient based on Occupation

Occupation	Group A		Group B		Total	
	N	%	N	%	N	%
Student	20	100.00%	20	100.00%	40	100.00%
Total	20	100.00%	20	100.00%	40	100.00%



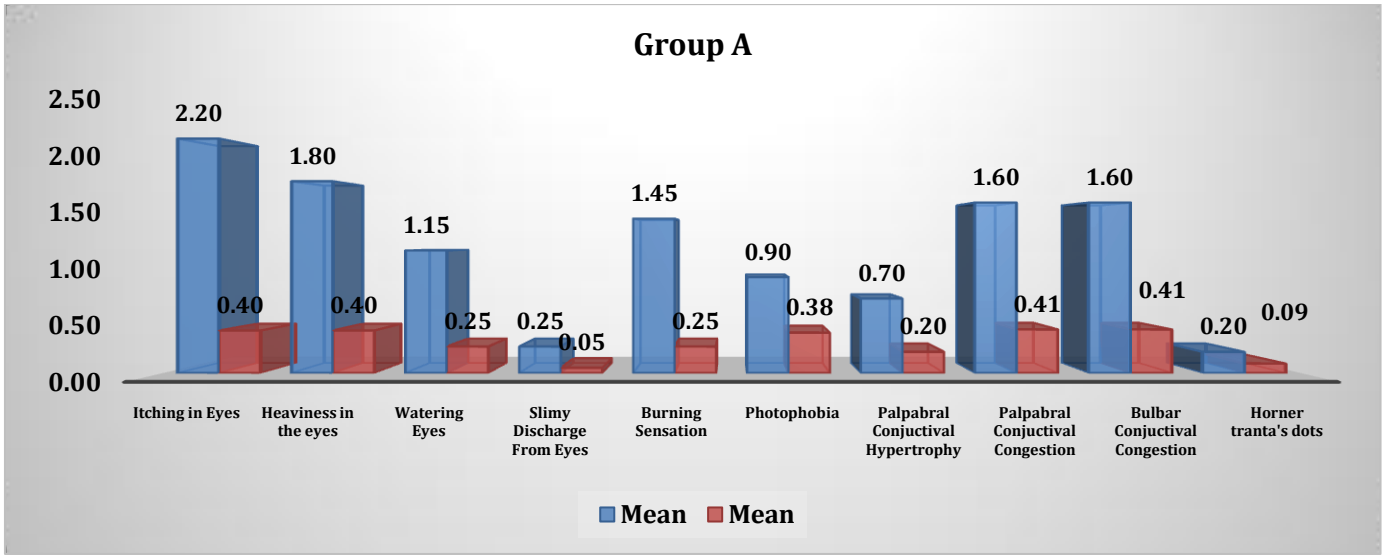
RESULT

All the results are calculated by using Software: In Stat Graph Pad 3.

1. For non-parametric data: Wilcoxon paired signed ranks test was used.
2. For calculating the Inter group comparison, Mann Whitney U Test was used.

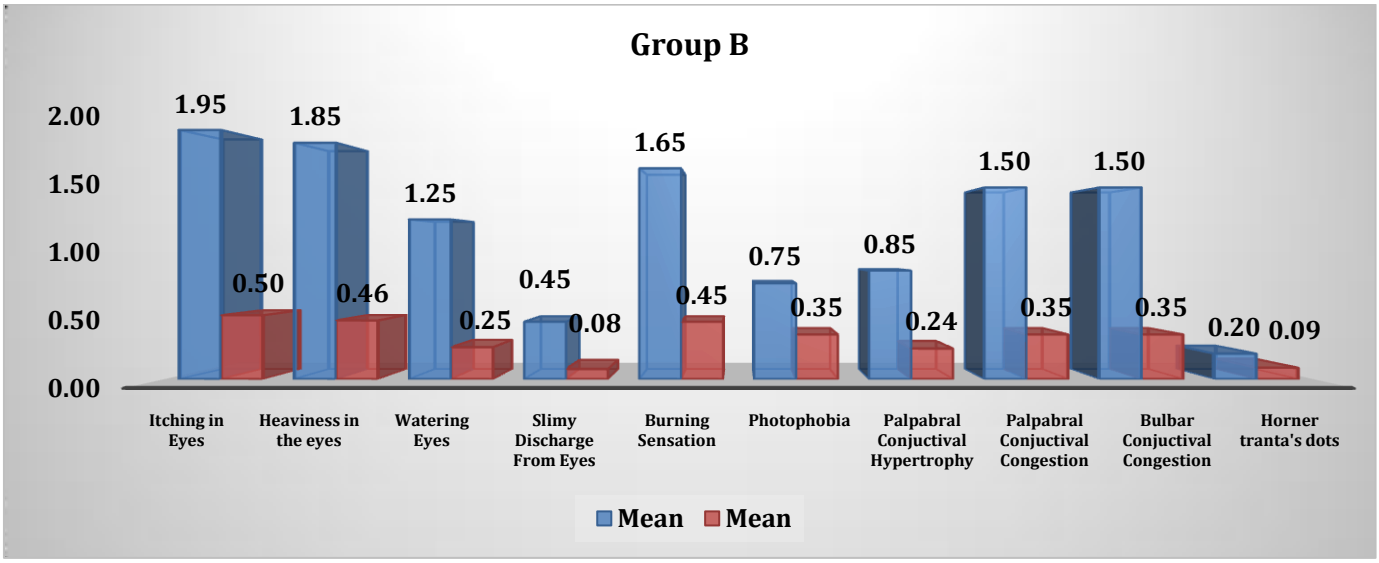
Showing Effect of Therapy on Group A on Assessment Parameters (Wilcoxon Paired Singed Ranks Test)

Group A	Mean		Median		SD		Wilcoxon W	P-Value	% Effect	Result
	BT	AT	BT	AT	BT	AT				
Itching in eyes	2.20	0.40	2.00	0.00	0.52	0.60	-4.093[b]	0.0000426	81.82	Sig
Heaviness in the eyes	1.80	0.40	2.00	0.00	0.62	0.60	-3.839[b]	0.0001237	77.78	Sig
Watering eyes	1.15	0.25	1.00	0.00	0.75	0.44	-3.626[b]	0.0002874	78.26	Sig
Slimy discharge From Eyes	0.25	0.05	0.00	0.00	0.55	0.22	-2.000[b]	0.0455003	80.00	Sig
Burning sensation	1.45	0.25	1.00	0.00	0.69	0.55	-4.021[b]	0.0000579	82.76	Sig
Photophobia	0.90	0.38	1.00	1.00	0.55	0.51	-2.646[b]	0.0081510	57.78	Sig
Palpabral conjuctival hypertrophy	0.70	0.20	1.00	0.00	0.73	0.41	-3.162[b]	0.0015654	71.43	Sig
Palpabral conjuctival congestion	1.60	0.41	1.50	0.00	0.68	0.47	-4.099[b]	0.0000415	74.38	Sig
Bulbar conjuctival congestion	1.60	0.41	1.50	0.00	0.68	0.47	-4.099[b]	0.0000415	74.38	Sig
Horner tranta's dots	0.20	0.09	0.00	0.00	0.52	0.31	-2.414[b]	0.0072992	55.00	Sig



Showing Effect of Therapy on Group B on Assessment Parameters (Wilcoxon Paired Signed Ranks Test)

Group B	Mean		Median		SD		Wilcoxon W	P-Value	% Effect	Result
	BT	AT	BT	AT	BT	AT				
Itching in Eyes	1.95	0.50	2.00	0.00	0.60	0.69	-4.053[b]	0.0000506	74.36	Sig
Heaviness in the eyes	1.85	0.46	2.00	0.50	0.67	0.68	-3.987[b]	0.0000668	75.14	Sig
Watering Eyes	1.25	0.25	1.00	0.00	0.91	0.60	-3.494[b]	0.0004755	80.00	Sig
Slimy Discharge From Eyes	0.45	0.08	0.00	0.00	0.76	0.37	-2.449[b]	0.0143059	82.22	Sig
Burning Sensation	1.65	0.45	2.00	1.00	0.67	0.51	-3.276[b]	0.0010540	72.73	Sig
Photophobia	0.75	0.35	1.00	1.00	0.44	0.50	-1.732[b]	0.0832645	53.33	NS
Palpabral Conjuctival Hypertrophy	0.85	0.24	0.00	0.00	0.99	0.51	-2.828[b]	0.0046777	71.76	Sig
Palpabral Conjuctival Congestion	1.50	0.35	1.50	0.00	0.51	0.50	-4.119[b]	0.0000381	76.67	Sig
Bulbar Conjuctival Congestion	1.50	0.35	1.50	0.00	0.51	0.50	-4.119[b]	0.0000381	76.67	Sig
Horner tranta's dots	0.20	0.09	0.00	0.00	0.41	0.37	-2.110[b]	0.0031731	55.12	Sig



Comparison between Group A and Group B

Variable	Group	N	Mean Rank	Sum of Ranks	Mann-Whitney U	P-Value
Itching in Eyes	Group A	20	24.20	484.00	126.000	0.0021
	Group B	20	16.80	336.00		
	Total	40				
Heaviness in the eyes	Group A	20	22.05	441.00	169.000	0.0346
	Group B	20	18.95	379.00		
	Total	40				
Watering Eyes	Group A	20	20.93	418.50	191.500	0.0795
	Group B	20	20.08	401.50		
	Total	40				

Slimy Discharge From Eyes	Group A	20	19.50	390.00	180.000	0.0471
	Group B	20	21.50	430.00		
	Total	40				
Burning Sensation	Group A	20	24.55	491.00	119.000	0.0012
	Group B	20	16.45	329.00		
	Total	40				
Photophobia	Group A	20	22.00	440.00	170.000	0.0262
	Group B	20	19.00	380.00		
	Total	40				
Palpabral Conjuctival Hypertrophy	Group A	20	21.50	430.00	180.000	0.0530
	Group B	20	19.50	390.00		
	Total	40				
Palpabral Conjuctival Congestion	Group A	20	22.35	447.00	163.000	0.0184
	Group B	20	18.65	373.00		
	Total	40				
Bulbar Conjuctival Congestion	Group A	20	22.35	447.00	163.000	0.0184
	Group B	20	18.65	373.00		
	Total	40				
Horner tranta's dots	Group A	20	21.00	420.00	190.000	0.0553
	Group B	20	20.00	400.00		
	Total	40				

Mann Whitney U Test is carried for comparison between Group A and Group B. From above table, we can observe that, P-Value for almost parameters is less than 0.05. Hence, we can conclude that, there is significant difference between Group A and Group B.

Analysis table for parameter of Group A and Group B

Parameter	**% Effect**	
	Group A	**Group B**
Itching in eyes	81.82	74.36
Heaviness in the eyes	77.78	75.14
Watering eyes	78.26	80.00
Slimy discharge from eyes	80.00	82.22
Burning sensation	82.76	72.73
Photophobia	57.78	53.33
Palpabral conjuctival hypertrophy	71.43	71.76
Palpabral conjuctival congestion	74.38	76.67
Bulbar conjuctival congestion	74.38	76.67
Horner tranta's dots	55.00	55.12
Average % effect	73.36	71.79

In group A, the average effect % is 73.36% and in group B, the average effect % is 71.79%.

Overall assessment of total effect

Overall Effect	Group A		Group B	
	N	%	N	%
Marked Improvement	12	60.00%	7	35.00%
Moderate Improvement	7	35.00%	6	30.00%
Mild Improvement	1	5.00%	7	35.00%
No Change	0	0.00%	0	0.00%
TOTAL	20	100.00%	20	100.00%

After analyzing data for total effect of therapy, following results were obtained.

Group A: Marked improvement was seen in 12 (60.00%) patients, moderate improvement was seen in 7 (35.00%) patients and mild improvement was seen in 1 (5.00%) patients.

Group B: Marked improvement was seen in 7 (35.00%) patients, moderate improvement was seen in 6 (30.00%) patients, mild improvement was seen in 7 (35.00%) patients.

DISCUSSION

The eyes are the most highly developed sensory organs of the body. It is described by Chanakya that one should take all efforts to save the eyes as this world is useless without eyes. *Acharya Sushruta* also explained 76 *Netra vyadhis* out of which *Abhishyanda* is classified under the *Sarvagata vyadhis*. According to *Acharyas*, *Abhishyanda* is produced when vitiated doshas are situated in all parts of the eyes. The symptoms of the specific disease involve *Kandu* (itching), *Guruta* (heaviness in the eyes), *Muhur-Muhur Srav* (repeated discharge from the eyes), *Pihchilla Srava* (ropy discharge), *Daha* (burning sensation), *Updeha* (stickiness due to increased exudates), *Ati Saityam* (excessive coldness). The etiology, clinical features and the prognosis of this disease i.e., *Kaphaja Abhishyanda* resembles with Vernal Kerato-conjunctivitis. The signs of VKC include Palpebral conjunctival hypertrophy, Palpebral conjunctival congestion, Bulbar conjunctival congestion, Horner-Tranta's dots.

General Observations

The average effect % in group A is slightly better than in group B. But as we see from the result that *Shigru Patra Arka Ashchyotana* has better relief in Itching, Heaviness, burning sensation and Photophobia in comparison to Olopatadine 0.1% eye drop whereas Olopatadine 0.1% eye drops has more relief in watering eyes, slimy discharge, palpebral conjunctival hypertrophy and congestion, bulbar conjunctival congestion and Horner Tranta's dots in comparison to Horner Tranta's Dots.

Mode of Action of Drugs

Administration of *Aschyotana* in eye

↓

Absorption of drugs through *Akshi* and *Sira srotas*

↓

Due to the properties of *Shigru patra* like *Kaphavatahara, Chakshushya, Raktapittahara*

↓ ↓

***Kaphavatahara* property**
Relief in symptoms like Itching, Heaviness, Slimy Discharge

***Raktapittahara* property**
Relief in symptoms like burning sensation, conjunctival congestion

↓

Improvement in sign and symptoms of the disease *Kaphaja Abhishyanda*

CONCLUSION

On Conceptual Study

- *Kaphaja abhishyanda* is one of the most common eye diseases affecting the humans in the present days.
- On the basis of signs and symptoms, *Kaphaja abhishyanda* can be correlated with Vernal keratoconjunctivitis.
- Among all the *Nidanas*, *Prasanga* which is applicable to all factors like physical contact, eating, sleeping together, sharing the same cosmetics or garlands is the most important *Nidana* of all.
- Among all the symptoms *Kandu* (itching in the eyes), *Guruta* (heaviness in the eyes), *Muhur muhursrav* (repeated discharge from the eyes) and *Pichhila* srava (ropy discharge from the eyes) can be correlated with the symptoms of Vernal keratoconjunctivitis.
- *Aupsargika roga karana* mentioned by Acharya Sushruta for *Abhishyanda* is at par with the explanations of modern pathology.

On Therapeutic Point of View

- *Aschyotana* is the preferred mode of application when considering the dose maintenance and it is easy and safe to administer.
- Due to busy lifestyle, patients want easy treatment modality. Eye drops is one of the most common forms of local drug use in ophthalmic practice.

On Drug Point of View

- *Shigru* which is described in the treatment of *Kaphaja Abhishyanda* by various *Acharyas*, is effective on the disease *Kaphaja Abhishyanda*.

On clinical study

- *Shigru patra arka ashchyotana* gave better results in the symptoms *Kandu* (itching in the eyes), *Guruta* (heaviness in the eyes), *Daha* (burning sensation), photophobia.
- Olopatadine 0.1% eye drop gave better results in watering eyes, slimy discharge, palpebral conjunctival hypertrophy and congestion, bulbar conjunctival congestion and Horner Tranta's dots.
- *Shigru* possesses *Tikta katu rasa*, *Tikshan* and *Laghu guna, Ushna virya, Katu vipaka*, Anti-bacterial, *Krimighana* and Anti-inflammatory properties which was helpful in combating symptoms of Vernal keratoconjunctivitis.
- Out of group A and group B, 12 patients in group A showed marked improvement, 7 showed moderate and 1 showed mild improvement. In group B of olopatadine eye drop 0.1%, 7 showed marked, 6 showed moderate, 7 showed mild and 0 patient showed no improvement.
- *Shigru patra arka aschyotana* is safe, economical and procedure is easy to perform.
- No any adverse effect was found during the study in *Shigru patra arka aschyotana*.

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